DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 2, 3, 6-10, 12-18, 20-24, 27, 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "preferably" and “in particular” in claims 2, 3, 6-10, 13, 15-17, 20-24, 27, 28 are a relative term which renders the claim indefinite. The term "preferably" and “in particular” are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

The recitations “preferably” and “in particular" constitute broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the

remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949).

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-5, 8-14, 19-21, 23 and 25-28 are rejected under 35 U.S.C. 102(b) as being anticipate by US Patent No. 3,328,259 to Anderson (Anderson).

Anderson teaches:

In Reference to Claim 1:

A planar implant (Fig. 1 & 2) comprising a planar support (Gauze 6, Fig. 1 & 2) with two faces (Fig. 1, upper and lower side of gauze), at least one face of the support being provided with an absorbable adhesive (Film 5, Fig. 1) layer which is able to adhere to human or animal tissue (Col. 3, lines 20-21) (Fig. 1, Col. 7, lines 58-61).

In Reference to Claim 2:

The implant as claimed in claim 1 (see rejection of Claim 1 above), characterized in that the adhesive layer (Film 5, Fig. 1) is essentially formed from

at least one polymer which carries free aldehyde groups and whose aldehyde groups are able to react with nucleophilic groups of the tissue (Col. 4, lines 44-45, polymer carries free aldehyde groups are derivatives of starch), and it in particular has anti-infective properties (Col.3, lines 26-27).

In Reference to Claim 3:

The implant as claimed in claim 1 (see rejection of Claim 1 above), characterized in that the adhesive layer (Film 5, Fig. 1) at least partially covers, preferably completely covers, the at least one face of the support (Fig. 1, Col. 7, lines 58-61).

In Reference to Claim 4:

The implant as claimed in claim 1 (see rejection of Claim 1 above), characterized in that the adhesive layer (Film 5, Fig. 1) is designed to cover the planar support only around the edges and/or to protrude beyond the edges (Fig. 1, protrude upwardly) of the planar support.

In Reference to Claim 5:

The implant as claimed in claim 1 (see rejection of Claim 1 above), characterized in that the adhesive layer (Film 5, Fig. 1) is provided on both faces of the support (Col. 9, lines 47-48).

In Reference to Claim 8:

The implant as claimed in claim 1 (see rejection of Claim 1 above), characterized in that the adhesive layer (Film 5, Fig. 1) is designed as an open layer (Col. 9, lines 47-48) and is in particular absorbent (Col. 6, lines 32-34).

In Reference to Claim 9:

The implant as claimed in claim 1(see rejection of Claim 1 above), characterized in that the adhesive layer (Film 5, Fig. 1) is hydrophilic and in particular is able to take up aqueous fluids by swelling (Col. 6, lines 32-34).

In Reference to Claim 10:

The implant as claimed in claim 1 (see rejection of Claim 1 above), characterized in that the adhesive layer (Film 5, Fig. 1) is present in the form of a nonwoven (Film 5, Fig. 1 & 2, Col. 1, lines 24-34,), in particular a three-dimensional nonwoven (The protective film 5 is "non woven" and "3-D").

In Reference to Claim 11:

The implant as claimed in claim 1 (see rejection of Claim 1 above), characterized in that the adhesive layer (Film 5, Fig. 1) is present in the form of an open-cell foam (Col. 6, lines 32-34).

In Reference to Claim 12:

The implant as claimed in claim 2 (see rejection of Claim 2 above), characterized in that the polymer carrying aldehyde groups is soluble in water (Col. 11, lines 1-8).

In Reference to Claim 13:

The implant as claimed in claim 2 (see rejection of Claim 2 above), characterized in that the polymer carrying aldehyde groups is an oxidized, in particular bioabsorbable polysaccharide (Col. 4, lines 44-45, starch is an oxidized polysaccharide).

In Reference to Claim 14:

The implant as claimed in claim 13 (see rejection of Claim 13 above), characterized in that the oxidized polysaccharide is one from the group comprising starch (Col. 4, lines 44-45), cellulose, agar, dextran aldehyde, hyaluronic acid, alginic acid, chondroitin sulfate, and preferably dextran polyaldehyde.

In Reference to Claim 19:

The implant as claimed in claim 1 (see rejection of Claim 1 above), characterized in that the adhesive layer has a structured surface (Gauze 6, Fig. 1) on its outer face.

In Reference to Claim 20:

The implant as claimed in claim 1(see rejection of Claim 1 above), characterized in that the planar support (Gauze 6, Fig. 1 & 2) is porous and flexible (Col. 1, lines 19-20), and in particular is formed from a textile material (Col. 2, lines 21-22).

In Reference to Claim 21:

The implant as claimed in claim 1 (see rejection of Claim 1 above),

characterized in that the support, in particular the textile support, is at least partially absorbable, in particular completely absorbable (Col. 3, lines 47-49).

In Reference to Claim 23:

The implant as claimed in claim 21 (see rejection of Claim 21 above), characterized in that the anti-adhesive layer contains polyvinyl alcohol and/or carboxymethylcellulose, and in particular consists of polyvinyl alcohol (Col. 4, lines 44-45).

In Reference to Claim 25:

The implant as claimed in claim 1 (see rejection of Claim 1 above), characterized in that it is designed as a patch (Fig. 1 & 2) which has the adhesive layer (Film 5, Fig. 1) on at least one face.

In Reference to Claim 26:

The implant as claimed in claim 2 (see rejection of Claim 2 above), characterized in that it is present as a tube section which is designed for connection of tubular hollow organs (Col. 9, lines 55-57)

In Reference to Claim 27:

Provision of the implant as claimed in claim 1 (see rejection of Claim 1 above), for an internal application in an organism (Col. 3, lines 46-49) in particular in the area of wounds.

In Reference to Claim 28:

Provision of the implant as claimed in claim 27 (see rejection of Claim 27 above), the planar support being connected on both faces to an adhesive layer (Film 5 & Gauze 6, Fig. 1) for apposition of vertical and horizontal tissue layers, the planar implant preferably being absorbable.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 6, 7, 22 & 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson in view of US Patent No. 6,319,264 to Tormala (Tormala).

In Reference to Claim 6:

Anderson teaches:

The implant as claimed in claim 1 (see rejection of Claim 1 above), characterized in that the support (Gauze 6, Fig. 1) has an adhesive layer (Film 5, Fig. 1) on one face.

Anderson fails to disclose:

An anti-adhesive layer on the other face.

Tormala teaches:

An anti-adhesive layer on the other face (2nd layer, Fig. 2) in order to prevent tissue adhesion (Col. 2, lines 7-10).

It would have been obvious to one having ordinary skill in the art at the time of the invention to have combined the implant of Anderson with the anti-adhesive layer of Tormala to produce an implant that only one layer has the ability to adheres to the injured area and the other layer has the ability to prevent adhesion to other tissues as explicitly taught by Tormala.

In Reference to Claim 7:

Tormala teaches:

The implant as claimed in claim 6 (see rejection of Claim 6 above), characterized in that the anti-adhesive layer has a closed and in particular smooth surface (2nd layer, Fig. 2, Col. 4, lines 61-63).

In Reference to Claim 22:

Anderson teaches:

The implant as claimed in claim 1 (see rejection of Claim 1 above).

Anderson fails to teach:

The implant as claimed in claim 1 characterized in that one face of the support is provided with at least one anti-adhesive layer which is preferably absorbable.

Tormala teaches:

that one face of the support is provided with at least one anti-

adhesive layer (2nd layer, Fig. 2) which is preferably absorbable (Col. 2, lines 35-38).

I would have been obvious to one having ordinary skill in the art at the time of the invention to have combine the implant of Anderson with the anti-adhesive layer which is absorbable of Tormala to produce an implant that could be use for internal bleeding.

In Reference to Claim 24:

Anderson teaches:

The implant as claimed in claim 1 (see rejection of Claim 1 above).

Anderson fails to teach:

in that it is designed as a hernia mesh having the adhesive layer on the face which is intended to bear on the abdominal wall, and in that the other face of the hernia mesh preferably has at least one layer which is designed as an anti-adhesive layer and prevents adhesion of body tissue to the mesh.

Tomala teaches:

An implant characterized in that it is designed as a hernia mesh (Col. 2, lines 35-36) having the adhesive layer on the face (1st layer, Fig. 2) which is intended to bear on the abdominal wall, and in that the other face of the hernia mesh preferably has at least one layer which is designed as an anti-adhesive layer (2nd layer, Fig. 2, Col. 2, lines 7-10) and prevents adhesion of body tissue to the mesh.

It would have been obvious to one having ordinary skill in the art at the time of the invention to have combined the implant of Anderson with the anti-adhesive layer of Tormala to produce an implant that only one layer has the ability to adheres to the injured area and the other layer has the ability to prevent adhesion to other tissues as explicitly taught by Tormala.

7. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson.

In Reference to Claim 15:

Anderson teaches:

> The implant as claimed in claim 14 (see rejection of Claim 14 above), characterized in that the glucose units oxidized to the aldehyde in the dextran polyaldehyde (Col. 4, lines 44-45).

Anderson fails to teach:

> The proportion of glucose units oxidized to the aldehyde in the dextran polyaldehyde is at least 20%, preferably 35 to 100%, in particular 50 to 85%.

Even though Anderson did not teach the exact percentage of the proportion of glucose units oxidized to the aldehyde in the dextran polyaldehyde group to form more covalent bonds for adhesive to the body tissues, the claim is rejected because it did not support the patentability of subject matter

encompassed by the prior. It is not inventive to discover the optimum ranges by routine experimentation.

8. Claims 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson in view of US Patent No. 7,179,660 to Kirakossian (Kirakossian).

In Reference to Claim 16:

Anderson teaches:

> The implant as claimed in claim 2 (see rejection of claim 2 above), characterized in that the polymer carrying aldehyde groups (Col 4, lines 44-45, polymer carries free aldehyde groups are derivatives of starch) is an in particular branched polyethylene glycol (Col. 7, lines 4-11).

Anderson fails to teach:

> The implant characterized in that the polymer carrying aldehyde groups is an in particular branched polyethylene glycol with at least three terminal aldehyde groups.

Kirakossian teaches:

> The implant as claimed in claim 2 characterized in that the polymer carrying aldehyde groups is an in particular branched polyethylene glycol with at least three terminal aldehyde groups (Col. 17, lines 33-35 and Col. 18, lines 27-30, multiple aldehyde groups have been known to use in the art (Kirakossian)).

It would have been obvious to one having ordinary skill in the art at the time

of the invention to have use the teaching of Anderson and combine with the teaching of Kirakossian to produce the implant with an adhesive layer that made up of the same chemical formula.

In Reference to Claim 17:

Anderson teaches:

> The implant as claimed in claim 2, (see rejection of claim 2 above), characterized in that the polymer carrying aldehyde (Col. 4, lines 44-45, polymer carries free aldehyde groups are derivatives of starch) groups is an in particular branched polyvinyl alcohol (The applicant admits the material are known for adhesive properties).

Anderson fails to teach:

> The implant characterized in that the polymer carrying aldehyde groups is an in particular branched polyvinyl alcohol with at least three terminal aldehyde groups.

Kirakossian teaches:

> The implant characterized in that the polymer carrying aldehyde groups is an in particular branched polyvinyl alcohol with at least three terminal aldehyde groups (Col. 17, lines 33-35 and Col. 18, lines 27-30, multiple aldehyde group have been known to use in the art (Kirakossian)).

It would have been obvious to one having ordinary skill in the art at the time of the invention to have use the teaching of Anderson and combine with the

teaching of Kirakossian to produce the implant with an adhesive layer that made up of the same chemical formula.

In Reference to Claim 18:

Anderson teaches:

The implant as claimed in claim 2 (see rejection of Claim 2 above).

Anderson fails to teach:

The implant characterized in that the at least one polymer carrying aldehyde groups is partially cross-linked.

Kirakossian teaches:

The implant characterized in that the at least one polymer carrying aldehyde groups is partially cross-linked (Col. 3, lines 30-31, cross-linked bonds are bonds that link one polymer chain to another, they can be covalent bonds or ionic bonds).

CONCLUSION

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Melican (US Patent No. 6,599,323) teaches a biocompatible tissue implant is bioabsorbable. Chun (US Patent No. 7,368,124) teaches a biocompatible tissue implant having a biocompatible reinforcement member.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SON DANG whose telephone number is (571)270-5809. The examiner can normally be reached on Monday-Friday 7:30 AM - 5:00 PM EDT.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ken Bomberg can be reached on 571-272-4922. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

11. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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